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Triamcinolone Diacetate

$C_{25}H_{31}FO_8$ 478.51

Pregna-1,4-diene-3,20-dione, 16,21-bis(acetyloxy)-9-fluoro-11,17-dihydroxy-, (11β,16α)-.

9-Fluoro-11β,16α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione 16,21-diacetate CAS RN®: 67-78-7; UNII: A73MM2Q32P.

» Triamcinolone Diacetate contains not less than 97.0 percent and not more than 103.0 percent of $C_{25}H_{31}FO_8$, calculated on the anhydrous basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Triamcinolone Diacetate RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: 20 µg per mL.

Medium: dehydrated alcohol.

Absorptivities at 238 nm, calculated on the anhydrous basis, do not differ by more than 3.0%.

Specific rotation ⟨781S⟩: between +39° and +45°.

Test solution: 5 mg per mL, in dimethylformamide.

Water Determination, *Method I* ⟨921⟩: not more than 6.0%.

Residue on ignition ⟨281⟩: not more than 0.5%.

Assay—

0.005 M Monobasic sodium phosphate solution—Dissolve monobasic sodium phosphate in water to obtain a solution containing 690 µg per mL.

Mobile phase—Prepare a mixture of *0.005 M Monobasic sodium phosphate solution*, acetonitrile, and tetrahydrofuran (62:37:1), filter through a 0.45-µm solvent-resistant filter, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Triamcinolone Diacetate RS in *Mobile phase*, and dilute quantitatively with *Mobile phase* to obtain a solution having a known concentration of about 40 µg per mL.

Assay preparation—Transfer about 50 mg of Triamcinolone Diacetate, accurately weighed, to a 50-mL volumetric flask, dissolve in *Mobile phase*, dilute with *Mobile phase* to volume, and mix. Pipet 2 mL of this solution into a second 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

System suitability preparation—Dissolve suitable quantities of USP Triamcinolone Diacetate RS and propylparaben in *Mobile phase* to obtain a solution containing about 40 µg per mL and 15 µg per mL, respectively.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *System suitability preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are 1.0 for triamcinolone diacetate and about 1.1 for propylparaben, the resolution, *R*, between the triamcinolone diacetate and propylparaben peaks is not less than 1.7, and the tailing factor, *T*, for the analyte peak is not more than 1.5. Chromatograph replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, and measure the area responses for the major peaks. Calculate the quantity, in mg, of $C_{25}H_{31}FO_8$ in the portion of Triamcinolone Diacetate taken

by the formula:

$$1.25C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Triamcinolone Diacetate RS in the *Standard preparation*, and r_U and r_S are the peak area responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
TRIAMCINOLONE DIACETATE	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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